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09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/821,821	Applicant(s) Welcher et al.
	Examiner Prema Mertz	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 16, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above, claim(s) *9, 12-50, and 56-69* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8, 10, 11, 51-55, 70, and 71* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-8, 10-11, 51-55, 70-71) in Paper No.7 (8/16/02) is acknowledged. The traversal is on the ground(s) that the restriction is improper since the examiner has not shown that examination of the protein of Group III with the DNA of Group I, would entail a serious burden. This is not found persuasive because the searches for the two Groups would not overlap, the inventions being classified in different classes and subclasses. Applicants are directed to MPEP.. 808.02 which states that "Where the related inventions as claimed are shown to be distinct and under the criteria of MPEP.. 806.05 (c-I), the examiner in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: 1) Separate classification thereof." In the instant case, Group I is classified in class 435, subclass 69.7 and Group III is classified in class 530, subclass 350.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and examine multiple inventions in a single invention. Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP.. § 806.05(f)). In the instant case the protein can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols. Therefore,

contrary to Applicants arguments, a search of the polypeptide claims of the instant invention would not necessarily provide information regarding the polynucleotide claims which inventions are distinct because a search of the literature for the polypeptide, would not be expected to reveal art for the polynucleotide encoding the polypeptide, which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP.. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP.. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicants have also asserted that claims 54-55 drawn to a fusion protein comprising the polypeptide of SEQ ID NO:2 fused to a heterologous amino acid sequence, be placed with Groups III and IV, rather than Groups I and II. However, contrary to Applicants assertions, the fusion proteins of claims 54-55, are produced by using the DNA of SEQ ID NO:1 and 3, to produce fusion proteins comprising the polynucleotide of SEQ ID NO:2 and 4, respectively. Therefore, the claims to fusion proteins will be examined with the claims to the nucleic acids.

The Groups as delineated in the restriction requirement (Paper No. 6, 7/10/02) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 9, 12-50, 56-69 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite the specific nucleic acid being claimed.

Claim objections

3. Claims 1-8, 10-11, 51-55, 70-71 are objected to because of the following informalities:

Claims 1-8, 10-11, 51-55, 70-71 are objected to, because they recite non-elected SEQ ID NO:3 and SEQ ID NO: 4.

Furthermore, claims 54-55 recite non-elected claims 13, 14, 15.

Appropriate correction to recite only the elected sequences and claims is requested.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 5-8, 10, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5-7 embrace a host cell in the body of a transgenic animal, or a host cell in a gene therapy patient. Claims 5-7 encompass human cells, fetuses and embryos, as well as non-human cells

including animals, vertebrates, mammals, primates, chimeric animals, germ cells (including oocytes and sperm), fertilized eggs, fetal tissues and organs. Claims 8, 10 are drawn to a method of producing such products. However, since it would that applicants do not intend to claim such human cells, or a process of producing such human cells, amending the claims to require non-human host cells and the hand-of-man would obviate this rejection i.e. an isolated non-human mammalian host cell.

Claim Rejections - 35 U.S.C. § 101/112

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1-8, 10-11, 51-55 and 70-71 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-8, 10-11, 51-55 and 70-71 are drawn to an invention with no apparent or disclosed patentable utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological

role of this protein or its significance. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

Claims 1-8, 10-11, 51-55 and 70-71 of the instant invention are directed to an isolated nucleic acid molecule comprising SEQ ID NO:1 encoding the protein comprising the amino acid sequence set forth in SEQ ID NO: 2. The specification on page 107, lines 29-34, discloses that Agp-69406-a1 cDNA was identified based on homology to a mouse gene (agp-65220-a1), and homology based searches identified a 428 nucleotide fragment which upon translation displayed homology to the human IgER/FCδRI. However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the protein encoded by the claimed nucleic acid molecule. Instant specification only discloses that the protein encoded by the claimed nucleic acid shares homology to human IgER/FCδRI (page 107, last 3 lines). The instant specification asserts that the claimed nucleic acid encodes a CD20/IgE-receptor like polypeptide but there is no demonstration or even a disclosure in the instant specification about the activities of the polypeptide encoded by the claimed nucleic acid. On page 15, lines 4-15, the specification recites that the term "biologically active CD20/IgE-receptor like polypeptide" refers to CD20/IgE-receptor like polypeptide having at least one activity characteristic of the polypeptide of SEQ ID NO:2 or 4. However, the specification does not demonstrate that the polypeptide encoded by the claimed nucleic acid actually displays any activity at all. Therefore, it is unclear from the instant specification, what the possible activity/activities of the polypeptide encoded by the claimed nucleic acid of SEQ ID NO:1 could be.

The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, if the instant polynucleotide and the protein it encodes are found to be members of the human IgER/FCδRI, they would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

5b. Claims 1-8, 10-11, 51-55, 70-71 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose any biological activity for the protein encoded by the claimed nucleic acid, therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The fact

that the claimed nucleic acid encodes a protein that has homology to human IgER/FCδRI is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 2 encoded by the polynucleotide of SEQ ID NO: 1, the instant specification would still fail to adequately describe and enable an isolated nucleic acid encoding a polypeptide that is at least about 70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to the polypeptide of SEQ ID NO: 2. Applicants do not teach which regions of said polynucleotide are critical to encode a functional polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 70% amino acid sequence identity to SEQ ID NO:2, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated nucleic acid encoding a polypeptide that is at least about 70% identical to the polypeptide of SEQ ID NO: 2, would be undue. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a

practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

5c. Claims 1-8, 10-11, 51-55, 70-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 1-8, 10-11, 51-55, 70-71 are genus claims. Claim 2, sub-part (b) recites "allelic variant or splice variant" which encompasses nucleic acid variants of the DNA encoding the protein of SEQ ID NO:2 and claim 2, sub-part (a), recites "an isolated nucleic acid encoding a polypeptide that is at least about 70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to the polypeptide of SEQ ID NO: 2" . The term variant refers a nucleic acid molecule encoding a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to the DNA molecule which encodes the amino acid sequence set forth in SEQ ID NO:2 (see page 13, lines 32-33;

page 14, lines 1-27; page 21, lines 24-33). The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the nucleic acid molecule. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid encoding a protein set forth in SEQ ID NO:2 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus of nucleic acid molecules.

Therefore only an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. As a result, it does not appear that the inventors were in possession of allelic variants of a polynucleotide of SEQ ID NO:1 or of an isolated nucleic acid

encoding a polypeptide that is at least about 70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to the polypeptide of SEQ ID NO: 2 as recited in claim 2.

5d. Claims 1-8, 10-11, 51-55, 70-71 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claims 1-3, the specification fails to provide a written description for "a nucleotide sequence which hybridizes under moderately or highly stringent conditions to the complement of ..., wherein the encoded polypeptide has an activity of the polypeptide as set forth in SEQ ID NO:2". Furthermore, no reasonable expectation of success and no working example of nucleotide sequences hybridizing to the nucleotide sequence encoding the protein comprising the amino acid sequence shown in SEQ ID NO:2, has been provided in the specification such that nucleic acids having substitutions, deletions, or addition corresponding to at least one amino acid residue would enable a protein of the biological characteristics of the CD20-IgE-receptor like protein. There is little to no guidance as to which of the hybridizing nucleic acid molecules would possess a biological activity. The current specification fails to disclose a single biological activity for the polypeptide encoded by the claimed nucleic acid. The specification provides only primary sequence data (i.e. SEQ ID NO. 2). No secondary or tertiary structure information is provided. Further, if the biological activity belongs to the fragment of the amino acid sequence of SEQ ID NO:2, the specification does not teach either which portion or which amino acids of the sequence are necessary

for activity. For these reasons, it does not appear that the inventors were in possession of nucleic acid molecules hybridizing under moderately or highly stringent conditions (as defined in pages 22-24) to the complement of the nucleic acid set forth in SEQ ID NO:1, which would encode a protein having a biological activity of SEQ ID NO:2.

Similarly, for the reasons recited above, with respect to claim 3, sub-part (a), which recites "at least one conservative amino acid substitution", sub-part (b), which recites "at least one conservative amino acid insertion", and sub-part (c), which recites "at least one conservative amino acid deletion", it does not appear that the inventors were in possession of a nucleic acid with "at least one conservative amino acid substitution", or a nucleic acid with "at least one conservative amino acid insertion", or a nucleic acid with "at least one conservative amino acid deletion" as recited in claim 3

Claim rejections-35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8, 10-11, 51-55, 70-71 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for several reasons.

Claim 1 is improper because in line 3, it recites "the" nucleotide sequence rather than "a" nucleotide sequence. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-3 recite "has an activity of the polypeptide of SEQ ID NO:2...", however, it is unclear what activity of the polypeptide is being referred to by the claims. The meets and bounds of the claims can not be ascertained.

Claim 2(c) recites "fragment of at least about 25 amino acid residues, wherein the polypeptide has an activity of the polypeptide set forth in SEQ ID NO:2". It is unclear whether the polypeptide fragment or the polypeptide itself has the activity.

Regarding claim 8, the term "optionally" renders the claim indefinite because it is unclear whether the limitations following the term are part of the claimed invention. See MPEP.. § 2173.05(d).

Claim 2(a) is rejected as vague and indefinite in their recitation of the limitation "about 70, 75, 80,..... percent identical...". The use of the term "about" in a claim is inherently vague and indefinite because it is unclear whether the percent identity if 50%, 60% or even 65%.

Claim 2(c), (d) are rejected as vague and indefinite in their recitation of the limitation "about 25 amino acid residues..." and "about 16 nucleotides" respectively. Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of indefinitely divisible units such as inches, meters, grams, and pints, where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino

acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a polynucleotide comprising a nucleotide sequence encoding 25 amino acid residues, then this is exactly what the claim should recite. One would not know if the term "about 25 amino acid residues" would include or exclude 10, 15 or 20 amino acids. Claim 3(f) which recites "a fragment of at least about 16 nucleotides" is rejected as vague and indefinite for the same reasons as claim 2(c) and (d) above.

Claims 1(c) and 2(e) recite "hybridizes under moderately or highly stringent hybridization conditions", which are relative and conditional terms and renders the claims indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. The metes and bounds of the claims thus cannot be ascertained.

Claim 3(a) recites "at least one conservative amino acid substitution", Claim 3(b) recites "at least one conservative amino acid insertion" and claim 3(c) recites "at least one conservative amino acid deletion". The claim is vague and indefinite because there is no upper limit for the number of amino acid substitutions, deletions or insertions recited in the claim. Similarly claim 3(e) is vague and indefinite because there is no upper limit for the number of amino acid substitutions, deletions or insertions, C-terminal truncation and N-terminal truncation recited in the claim.

Claims 51 and 53 are vague and indefinite because it recites "of claims 1, 2 or 3" rather than "any one of claims 1, 2, or 3".

Claims 4-8, 10-11, 51-55 and 70-71 are rejected as vague and indefinite insofar as they depend on claims 1-3 for their limitations.

Claim rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hillier et al. (1997). Hillier et al. teach a cDNA clone with 99.6% homology to human B-lymphocyte antigen CD20. A copy of the comparison of SEQ ID NO:1 claimed in the instant invention and the nucleotide sequence of the reference is enclosed at the end of this action (SEQUENCE COMPARISON "A"). Therefore, the nucleic acid described in the reference is capable of hybridizing under moderately stringent conditions to the nucleic acid encoding the polypeptide of SEQ ID NO:2 as in the present invention, meeting the limitations of claims 1(c), 2(e) and 3(g). Furthermore, the nucleic acid described in the reference comprises a fragment of at least about 16 nucleotides of SEQ ID NO:1 of the instant invention, meeting the limitations of claims 2(d) and 3(f). Therefore, the nucleotide sequence disclosed in the reference meets the limitations of a nucleic acid as recited in claims 1, 2 and 3 of the instant invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 4-8, 10-11, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (1997).

The disclosure of Hillier et al has been set forth above in paragraph 7. However, Hillier never produced the protein encoded by the cDNA.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to place the DNA disclosed by Hillier et al., in an expression vector and host cell which expresses the putative receptor protein encoded thereby, and recovering the recombinant protein produced. To have incorporated the recombinant DNA encoding the protein identified by Hillier et al, into an expression vector and host cell to facilitate the production and characterization of the protein encoded thereby by employing those methods that were old and well known in the art of molecular biology at the time that the instant invention was made would have been *prima facie* obvious to an artisan in light of the Hillier et al publication. Furthermore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to merely

admix a carrier with the nucleic acid, and obtaining such does not render the resulting composition patentable if it would have been obvious to formulate the nucleic acid with a pharmaceutically acceptable carrier relative to its art intended use.

8b. Claims 54-55 are rejected under 35 U.S.C. § 103 as being unpatentable over Hillier et al (1997) in view of Capon et al. (U.S. Patent No. 5,116,964).

The disclosure of Hillier et al. has been set forth above (see paragraph 7). However, Hillier et al. does not teach a receptor polypeptide fused to a heterologous polypeptide, wherein said heterologous polypeptide comprises an IgG constant domain (an antibody Fc region).

Capon et al. teaches chimeric proteins for directing ligand binding partners such as receptors, growth factors, hormones or effector molecules to cells bearing ligands for the ligand binding partners comprising a ligand binding partner fused to a stable plasma protein which is capable of extending the in vivo half-life of the ligand binding partner when present as a fusion with the ligand binding partner, in particular wherein such a stable plasma protein is an immunoglobulin constant domain (see column 4, lines 38-47, 57-64; column 5, lines 11-21; column 7, lines 11-27).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art to modify the polypeptide encoded by the nucleic acid claimed in the instant invention such that it includes the polypeptide bonded to the Fc region of an IgG molecule to obtain a chimeric protein with an increased circulating half-life, as taught by Capon et al., to obtain the known functions and advantages of the protein molecule encoded by the claimed nucleic acid molecule. It would be obvious to substitute the instant polypeptide (encoded by the claimed nucleic acid) in the chimeric

protein, to improve the therapeutic potential of the polypeptide molecule. One would have been motivated to use a chimeric protein comprising the polypeptide encoded by the instantly claimed nucleic acid and Fc to decrease its clearance rate *in vivo*. Therefore, it would have been obvious to fuse the polypeptide encoded by the nucleic acid of the instant invention to Fc, a long-lived molecule well known in the art as able to increase the stability of rapidly cleared molecules.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz Ph.D.
Patent Examiner
Art Unit 1646
October 9, 2002